



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,070	07/10/2006	Barry J. Sender	52023-00001	5527
45200	7590	05/13/2010		
K&L Gates LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319				
EXAMINER				
NGUYEN, TRANG T				
ART UNIT		PAPER NUMBER		
3686				
NOTIFICATION DATE		DELIVERY MODE		
05/13/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ocipgroup@klgates.com
maria.nadal@klgates.com

Office Action Summary

Application No.

10/597,070

Applicant(s)

SENDER ET AL.

Examiner

TRANG NGUYEN

Art Unit

3686

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8-10,12,13,16,18,20-22,24-28,31,34-36,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8-10,12,13,16,18,20-22,24-28,31,34-36,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/10/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-646)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/19/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 07/10/2006.
2. Claims 1, 2, 5, 8-10, 12, 13, 16, 18, 20-22, 24-28, 31, 34-36, 38 and 39 are currently pending and have been examined.
3. Claims 3, 4, 6, 7, 11, 14, 15, 17, 19, 23, 29, 30, 32, 33 and 37 are cancelled,

Drawings

4. The drawings were received on 07/10/2006. These drawings starting from Figures 5 - 36 are objected because they are not clear. Appropriate correction is requested.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 07/19/2006 is entered and considered by Examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 12, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. A claim can not refer to a figure within the body of a claim. Appropriate correction is requested.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 39 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 39 is directed to a method. However, the recited steps of the method are held to be non-statutory subject matter because the recited steps of the method are (1) not tied to another statutory class (such as a particular apparatus) or (2) not transforming the underlying subject matter (such as an article or materials) to a different state or thing.

10. Claims 1, 2, 5, 8-10, 12-13, 16, 18, 20-22, 24-26 and 31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A claim directed to or including within its scope a human being (i.e. data collection means and interpretation means) will not be considered to be patentable subject matter under 35 U.S.C. 101. Appropriate correction is required.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1, 2, 5, 8, 12, 13, 16, 18, 20, 24, 27, 28, 31, 34, 38 and 39 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Linberg et al. (US 20010039504 A1A1).

Regarding claims 1, 12, 24 and 39:

Linberg as shown discloses the following limitations:

A disease management system comprising:

data collection means (See at least paragraph 0175);

data interpretation means (See at least paragraph 0012); and

therapeutic dispensing means, wherein said data collection means is used

to obtain disease state information from a patient having a disease wherein said

patient is located remotely relative to said data interpretation means and said therapeutic dispensing means and wherein said data interpretation means is located on a computer-readable medium and provides diagnostic, prognostic and therapeutic information useful for the management of said disease of said patient
(See at least claim 19, paragraphs 0008-0009, 0012, 0175).

Linberg discloses gathering and transferring data into a data management center where the data may be analyzed, with relevant therapy/clinical care dispensed accordingly (paragraph 0012); Linberg also discloses connecting the client with care providers irrespective of separation distance or location of the participants; furthermore the connection to a remote expert data center is disclosed in paragraph 0008.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Linberg so as to have claimed the patient is located remotely relative to said data interpretation means and said therapeutic dispensing means and said data interpretation means is located on a computer-readable medium, in order to provide therapeutic information useful for the management of the disease of a patient to have improved the efficiency of the system, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Regarding claims 2, 13 and 28 Linberg further discloses:

The disease management system of claim 1 wherein said data collection means comprises a non-physician healthcare worker or a laboratory (See at least abstract,

paragraphs 0010, 0185).

Regarding claims 5, 16 and 31 Linberg further discloses:

The disease management system of claim 1 wherein said data interpretation means comprises an algorithm or a physician specialist (See at least paragraph 0175).

Regarding claims 8, 20 and 34 Linberg further discloses:

The disease management system of claim 1 wherein said therapeutic dispensing means comprises a pharmacy (See at least paragraph 0109).

Regarding claim 18:

The disease management system according to claim 16 wherein said algorithm is stored on a computer-readable medium.

Linberg discloses an analysis algorithm (See at least paragraph 0175) and a computerized method of collecting and utilizing distributed patient and clinician data (See claim 4). This suggests that the analysis algorithm is stored on the computer readable medium. Furthermore, it is old and well known in the art to store (computational) algorithm on a computer-readable medium in order to use a computer to process data. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Linberg so as to have stored the algorithm on a computer-readable medium, in order for the computer to interpret

data and to provide therapeutic information useful for the management of a particular disease (e.g. HIV or AIDS) of a patient, to have improved the efficiency of the system], since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Regarding claim 27:

A method for managing disease in a patient located remotely relative to data interpretation means and therapeutic dispensing means comprising:

collecting a first set of data from said remotely located patient;
interpreting said first set of data in order to determine an appropriate first therapeutic regimen for said remotely located patient;
dispensing said first therapeutic regimen to said remotely located patient;
collecting at least one second set of data from interpreting said at least one second set of data in order to determine the appropriateness of continuing or stopping said first therapeutic regimen or altering said first therapeutic regimen for said remotely located patient; and
wherein said first and at least one second interpreting step comprises an algorithm located on a computer-readable medium that provides diagnostic, prognostic and therapeutic information useful for the management of said disease of said patient (See at least claim 19, paragraphs 0008-0009, 0012, 0175).

Linberg discloses gathering and transferring data into a data management center where the data may be analyzed, with relevant therapy/clinical care dispensed accordingly (paragraph 0012) – this suggest the determination of the appropriateness of continuing or stopping the therapeutic regimen or altering the therapeutic regimen for a patient; Linberg also discloses connecting the client with care providers irrespective of separation distance or location of the participants; furthermore the connection to a remote expert data center is disclosed in paragraph 0008.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Linberg so as to have included first and second interpretation steps, in order to provide therapeutic information useful for the management of the disease of a patient to have improved the efficiency of the system, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Regarding claim 38 Linberg further discloses:

The method for managing disease in a patient according to claim 27 wherein said algorithm is the algorithm of Figure 4 (See at least claim 19, paragraphs 0008-0009, 0012, 0175).

14. Claims 9, 21, 25 and 35 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Linberg et al. (US 20010039504 A1A1) in view of Barry (US 6188988 B1).

Linberg does not disclose the following limitation. However, Barry discloses:

Regarding claims 9, 21 and 35:

The disease management system of claim 1 wherein said computer-readable medium is a selected from the group consisting of hard drives, floppy disks, CD-ROMs, zip drives and flash drives (See at least column 4, lines 16-29).

Regarding claim 25:

The disease management system of claim 24 wherein said data comprises a patient history and CD4 levels (See at least column 4, lines 59-67; column 5, lines 1-9; column 13, lines 39-52).

Furthermore, it is old and well known in the art to use hard drives, floppy disks, CD-ROMs, zip drives or flash drives as computer-readable medium. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Linberg so as to have included patient data comprises a patient history and CD4 levels, in accordance with the teaching of Barry, in order to provide therapeutic information useful for the management of a particular disease (e.g. HIV or AIDS) of a patient, to have improved the efficiency of the system], since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

15. Claims 10, 22, 26 and 36 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Linberg et al. (US 20010039504 A1A1) in view of Sperber (US 20040197770 A1).

Linberg does not disclose the following limitation. However, Sperber discloses:

Regarding claims 10, 22 and 36:

The disease management system of claim 1 wherein said disease is human immunodeficiency (HIV) disease or acquired immune deficiency syndrome (AIDS) (See at least abstract, paragraph 0010).

Regarding claim 26:

The disease management system of claim 24 wherein the therapy comprises High Activity Anti-Retroviral Therapy (HAART) (See at least paragraphs 0010, 0020, 0290).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Linberg so as to have included HIV or AIDS as the disease and HAART as the therapy for the disease, in accordance with the teaching of Sperber, in order to provide therapeutic information useful for the management of the particular disease (e.g. HIV or AIDS) of a patient, to have improved the efficiency of the system], since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **TRANG NGUYEN** whose telephone number is **(571) 270-5483**. The Examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **GERALD O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to **(571) 273-8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window:**

Randolph Building
401 Dulany Street
Alexandria, VA 22314.

/T. N./
May 06, 2010
Examiner, Art Unit 3686

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686